REMARKS

Claims 2 to 12, 15, 32, 35 to 38 are being examined of which claims 6, 32 and 35 and 36 are in independent form. Claim 38 is new. Claims 1, 13, 14 and 26 to 29 are cancelled. Claims 16 to 25, 30 to 31 and 33 to 34 are withdrawn from consideration. Claim 32 is being examined for the embodiment of "diagnosis or monitoring." SEQ ID NO: 3 is the elected species.

Withdrawn Objections and Rejections

Applicants would like to thank the Office for withdrawing the objections and rejections as highlighted on pages 2 and 3 of the action.

New Objections

On page 3, the Office raises new objections to claims 9, 11 and 32 in view of the following informalities:

In claim 9, line 8 "is detected" should be -are detected--.

In claim 11, line 7 "bind" should be -binds--.

In claim 32, line 1, --or-- needs to be inserted after "diagnosis".

The claims have been amended in accordance with the Office's suggestion.

On page 4, the Office objected to claim 10 to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Office in particular stated that claim 10 fails to further limit base claim 1, because step a) of claim 1 serves to concentrate and/or purify the autoantibodies.

Applicants have amended the claim into introduce the term "further" before "concentrated." Support for this amendment can be found on page 11, the last two paragraphs of the specification. The example in the last paragraph of this page makes clear that the concentration or purification is a further concentration or purification (see also "doctrine of claim differentiation" and wording of original claim 10) and makes also clear that this additional concentration and/or purification takes place before the autoantibody is contacted with any tag.

35 USC 112, second paragraph rejections

Also on page 4, the Office rejected all currently examined claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Claim 1 was rejected for being incomplete for omitting essential steps. The omitted steps are said to be the following: "between steps a) and b) applicant has disclosed the essential step in which the separated components [i.e. the precipitated autoantibodies] can be returned to essentially the native state that allows their detection." The Office expressed the opinion that unless the precipitated autoantibodies are returned to their native state, these autoantibodies will not bind to the peptide that is added in step b). The Office referred to page 6, second full paragraph of the specification.

Claim 1 is cancelled. However, in response to this rejection, applicants have included in newly independent claims 6 and 36, and in accordance with the Office's suggestion, a reference to the return of the autoantibodies into essentially the native state (see page 6, second full paragraph).

The Office also reiterated the rejection of claim 10 under 35 USC 112, second paragraph as outlined in the previous Office Action. The Office expressed the opinion that it is unclear when the concentration or purification recited in the claim takes place.

Claim 10 has been further amended to clarify that the recited purification or concentration takes place before b). For support, please see applicant's response to the objection to this claim (above, last paragraph of page 12 of this response).

Claims 32 and 35 are said to be indefinite by not setting forth any steps involved in the method/process.

The Office noted that in claim 35, at least, "bringing a bodily fluid into contact with a provided peptide, whereby autoantibodies bind said peptide" has been omitted as such a step. This omitted step was said to be required after the "providing" step. Furthermore, the

"detecting" step of claim 35 was said to have no nexus to the rest of the claim. The Office suggested that applicants recite: detecting said autoantibodies bound to said peptide.

Claim 32 was said to be likewise incomplete. For the embodiment in which a peptide of part a) is provided (which is the only embodiment under consideration), claim 32 was said to need to be amended similarly as suggested for claim 35 above. The Office also expressed the opinion that claim 32 would also require a step that relates the detection of autoantibodies for the diagnosis of or the progression of said autoimmune disease.

The claims have been amended in accordance with the Office's suggestions.

35 USC 112, first paragraph rejections

On page 6, the Office reiterated the rejection of claim 15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as outlined in the previous Office Action. In response to applicant's previous argument, the Office stated that the fact that the person skilled in art is able to make recited deletions, additions or substitutions is not sufficient in the context of a written description rejection.

Applicants note that the application specifically refers to deletions, additions, and/or substitutions used in the claims (see page 13, first full paragraph) and in original claim 15. The application text also provides guidance, e.g., on pages 8 and 17 as to how these deletion, addition, and/or substitution can be made.

Applicants note that there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims").

The above noted paragraphs of the specification also make clear that there is an art-recognized correlation/relationship between the structure of the invention and its function.

Applicants also note the Written Description Training Material that issued in March 2008 notes on page 1 that a determination as to whether one skilled in the art would recognize that the applicant was in possession of the claimed invention should include the following considerations:

a. Actual reduction to practice
b. Disclosure of drawings or structural chemical formulas
c. Sufficient relevant identifying characteristics, such as:
    i. Complete structure
    ii. Partial structure
    iii. Physical and/or chemical properties
    iv. Functional characteristics when coupled with a known or disclosed correlation between function and structure
d. Method of making the claimed invention
e. Level of skill and knowledge in the art
f. Predictability in the art. *(emphasis added)*

Applicants respectfully submit that the level of skill and knowledge in the art is high (e) and that methods of making the appropriate deletions, additions or substitutions are well known in the art (d). In addition, the functional characteristics of the deletions, additions or substitutions are coupled to a known or disclosed correlation between structure and function (c). Also, as discussed previously (page 18 of applicant's last response), the person skilled in the art had knowledge about how to produce the claimed peptides from seed peptides and the specification specifically directs the reader to this fact (page 17, first full paragraph, page 8, first and second full paragraph of the specification). Last, but not least, a wide range of "partial structures" of the claimed sequences have been disclosed and their physical properties are discussed in detail throughout the specification.

Accordingly, applicants respectfully submit that they demonstrated possession of the claimed invention and that the written description requirement has been met.

On page 7, the Office rejected claims 1 to 15 under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The Office expressed the opinion that a step,

between steps a) and b) in claim 1, in which "the separated components [i.e. the precipitated autoantibodies] can be returned to essentially the native state that allows their detection" is said to be critical or essential to the practice of the invention, but it has not been included in the claim(s).

Without conceding the veracity of these statements, as outlined above, appropriate language as requested by the Office was introduced in new independent claims 6 and 36. Accordingly, the Office enablement concerns should be fully addressed.

ART REJECTIONS

Stating on page 9, the Office reiterated the rejection of claims 32 and 35 under 35 U.S.C. 102(b) or (e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either Wallukat et al (1995) or Ronspeck (e.g., WO 01/21660), as outlined in the previous Office Action.

In response to the Office's observation in the paragraph bridging pages 9 and 10 of the Action, applicants have amended claim 32 to recite the diseases diagnosed and monitored as well as claim 35 to recite the targets of the auto-antibodies detected, into the body of the claim. Applicants submit that these changes clearly overcome the anticipation/obviousness rejection for the reasons recited in the previous response, pages 19 to 23.

On page 10, the Office rejected claims 1-5, 7-10, 15 and 37 under 35 U.S.C. 102(a) or (b) as being entirely anticipated by Wallukat et al (In vitro Cellular . . . , Vol. 38, 376-77 (August 02) (hereinafter "Wallukat 2002").

Claim 1 was cancelled and all claims of the rejection are now directly or indirectly dependent on non-rejected claim 6 which incorporates all limitations of claim 1 (as does claim 36, which was also not rejected). Accordingly, the anticipation rejection is moot.

On page 11, the Office rejected claims 12, 32 and 35 under 35 U.S.C. 103(a) as being unpatentable over Wallukat 2002 in view of Wallukat et al (WO 00/39154, cited in IDS of 1/27/09).

Claim 12 is now dependent on claim 6 and reference to SEQ ID: 9 and 10 noted by the Office have been removed from the claim. As a result, even under the assumption that the Office's obviousness analysis is correct, which applicants do not admit, not all elements of the claimed invention are disclosed in the Wallukat 2002 reference. Thus, no *prima facie* case of obviousness has been established with regard to claims 12 as amended.

Claims 32 and 35 have been amended as discussed above and recite in particular a detecting step that the Office noted to be missing in this rejection. Applicants submit that these claims have been amended to include such detecting steps, thus removing the basis on which these obviousness rejections of claims 32 and 35.

Information Disclosure Statement

Applicants would like to thank the Office for noting that certain references cited in the previously submitted IDS of 1/27/09 were already of record. With regard to DE19826442 ("A" reference in ISR) and WO2004067549 ("T" reference in ISR), applicants note that these references were cited in the International Search Report (ISR), which was submitted with the IDS and was in English (see in particular page 4 of the submitted ISR). Applicants respectfully note the provisions of MPEP 609.04(a)III. Here the MPEP states that "[w]here the information listed is not in the English language, but was cited in a search report or other action by a foreign patent office in a counterpart foreign application, the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office. This may be an explanation of which portion of the reference is particularly relevant, to which claims it applies, or merely an "X", "Y", or "A" indication on a search report." Consideration of these references is thus respectfully requested.

In view of the above amendments and arguments, applicants believe that all claim rejections and objections have been fully addressed and an early notice of allowance is respectfully requested. The Office is urged to call the undersigned at (301) 657-1282 for any issues that might remain.

No fee is believed to be due in addition to extra claim fees and the extension of time fee paid herewith. However, the Commissioner is authorized to charge or credit deposit account no. 50-3135 as required. Any petition that may be required for the consideration of this response is herewith respectfully requested.

Respectfully submitted,

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September 11, 2009